

**National Institutes of Health – Office of Research on Women’s Health
U.S. Food & Drug Administration – Office of Women’s Health**

**25th Anniversary Congress on Women’s Health
2017 Pre-conference Symposium**

**Working Together to Address Women's Health in Research and Drug
Development: Challenges and Opportunities**

Thursday, April 27, 2017

2:30 – 5:00 P.M.

At the 25th Anniversary Congress on Women’s Health, April 27-30, 2017

Crystal Gateway Marriott Hotel

1700 Jefferson Davis Highway

Arlington, Virginia 22202

Space is limited so please follow your IC’s process for requesting to attend the full event or register for free pre-conference Symposium by clicking here
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AGENDA

2:30 PM – 2:40 PM -WELCOME AND OPENING REMARKS

Janine Austin Clayton, MD

NIH Associate Director for Research on Women’s Health

Director, Office of Research on Women's Health (ORWH), NIH

Marsha Henderson, MCRP

FDA Assistant Commissioner for Women’s Health

Director, Office of Women’s Health (OWH), FDA

Past Accomplishments: 2:30 PM – 3:20 PM

2:40 PM – 3:00 PM - WOMEN’S HEALTH INITIATIVE

Michael S. Lauer, MD

NIH Deputy Director for Extramural Research

**3:00 PM – 3:20 PM - PROGRESS IN INCLUDING WOMEN IN CLINICAL TRIALS FOR FDA-
APPROVED PRODUCTS**

Pam Scott, PhD, MA

Deputy Director and Director of Research and Development, Office of Women’s Health, FDA

Present Endeavors: 3:20 PM – 4:00 PM

3:20 PM – 3:40 PM - NICHD CLINICAL TRIALS IN PREGNANT WOMEN: ILLUMINATING, PATH-BREAKING, AND HUMBLING (NO KIDDING!)

Tonse N. K. Raju, MD, DCH

Chief, Pregnancy and Perinatology Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH

3:40 PM – 4:00 PM - FDA PREGNANCY UPDATES: DRUG LABELING, REGISTRIES, AND CLINICAL TRIALS

Tamara Johnson, MD, MS

Team Leader, Maternal Health Team, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, FDA

Future Directions: 4:00 PM – 4:40 PM

4:00 PM – 4:20 PM - PRECISION MEDICINE INITIATIVE: PRECISION FOR WOMEN

Stephanie Devaney, PhD

Deputy Director, Precision Medicine Initiative *All of Us* Research Program, NIH

4:20 PM – 4:40 PM - EXPANDING FDA TRANSPARENCY AND COMMUNICATIONS: WHAT EVERY PROVIDER SHOULD KNOW

Milena Lolic, MD, MS

Medical Officer, Professional Affairs and Stakeholder Engagement, Center for Drug Evaluation and Research, FDA

Closing

4:40 PM – 4:55 PM - DISCUSSION, QUESTIONS, AND ANSWERS

4:55 PM – 5:00 PM - CLOSING REMARKS

Marjorie Jenkins, MD, MEdHP, FACP

Director of Medical Initiatives and Scientific Engagement, Office of Women's Health, FDA